system will ''power'' an oxygen delivery tent. The association stated that such a pneumatic powered oxygen tent falls within the classification of an oxygen administration system which must satisfy certain criteria and specifications. According to the association, review of premarket notification submissions is the only way to ensure that these devices conform to these criteria and specifications. Thus, the association concluded, these devices should not be exempt from the premarket notification requirements.

D. Anesthetic Warmer (§ 872.6100)

This comment was concerned that the words ''anesthetic warmer'' could be applied literally to refer to certain anesthesiology devices associated with known cases of injury, device failure, and misuse. Further, the comment stated that ''anesthetic warmer'' could be applied to anesthesiology devices which are required to follow performance and/or safety specifications.

FDA agrees that the breathing mouthpiece (§ 868.5620); the rebreathing device (§ 868.5675); and the nonpowered oxygen tent (§ 868.5700) should not be exempt from the requirement of premarket notification. Thus, the agency is withdrawing the proposed exemptions for these devices because these devices have a significant history of risk and/or characteristics of the devices necessary for their safe and effective performance are not well established. However, FDA has concluded that the anesthetic warmer (§ 872.6100) should be exempt from the requirement of premarket notification. Moreover, FDA believes that the identification of this device is sufficiently clear to exclude the devices referred to in the comment.

III. Reconsideration of the Appropriateness or Scope of the Exemptions

FDA reconsidered the appropriateness of exempting cultured animal and human cells (§ 864.2280) from the requirement of premarket notification.

FDA is withdrawing the proposed exemption for this device because, upon reconsideration, the agency has determined that the device does not meet the exemption criteria. The device is comprised of either continuous cell or primary cell lines for the isolation and identification of various pathogenic organisms. If the cells are continuous lines, it must be assured that a mechanism is in place for the manufacturer to determine that the cell line has not changed from the original cell type. After prolonged passages cell lines will deviate from the original cell line and the sensitivity for isolation of organisms is decreased. On the other hand, if the cell line is primary, there must be assurance that the cell line is not contaminated with adventitious organisms which may preclude the isolation or identification of the pathogen from the patient. Sometimes it is not readily apparent whether the cells are contaminated with adventitious organisms. Furthermore, with the advent of genetically engineered cell lines for identification of specific organisms, information must be reviewed to determine whether the genetically engineered cell lines will function as claimed. Also, it must be assured that the labeling is consistent with the effectiveness and use of the specific cell. If an applicant wishes to make effectiveness or use claims which are not supported in the literature, appropriate studies are required to validate these claims. If the device is inappropriately labeled, the risk of incorrect diagnosis or ineffective treatment may be increased.

Upon reconsideration, FDA is withdrawing the proposed exemption for the lactoferrin immunological test system (§ 886.5570) because it is anticipated that there may be significant changes to this device that could affect its safety and effectiveness. Such changes could involve new intended uses and new matrices for which the agency has no information or data. The device is not well characterized and any anticipated changes that could affect safety or effectiveness are not readily detectable by any means and could increase the risk of incorrect diagnosis. Similarly, it must be assured that the labeling for the device is appropriate and accurate for the proposed claims. If the device is not appropriately labeled and the performance established, there may be an increased risk of misdiagnosis.

FDA is also withdrawing the proposed exemption for the thin-layer chromatography system for clinical use (§ 862.2270). Upon further review, FDA has determined that any anticipated changes that could affect the safety and effectiveness of the device are not readily detectable by any means and could materially increase the risk of incorrect diagnosis.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a) (21 U.S.C. 360c and 371(a)) and under 21 CFR 5.10, the proposed rule published in the **Federal Register** of July 21, 1994, is withdrawn with respect to the 7 devices cited in Table 2 of this document.

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–18457 Filed 7–27–95; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. 95N–0139]

Medical Devices; Proposed Reclassification and Exemption From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify 112 generic types of class II devices into class I based on new information respecting such devices. FDA is also proposing to exempt the 112 generic types of devices, and 12 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. For the devices for which exemptions are being proposed, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. Granting the exemptions will allow the agency to make better use of its resources and thus better serve the public.

DATES: Submit written comments by October 11, 1995. For the devices the agency is proposing to reclassify into class I and exempt from the requirement of premarket notification, FDA is proposing that any final rule that may issue based on this proposed rule become effective August 28, 1995.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et. seq.*), as amended by the Medical Devices

Amendments of 1976 (Pub. L. 94–295, hereinafter called the amendments) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, special controls; and class III, premarket approval.

The effect of classifying a device into class I is to require that the device meet only the general controls which are applicable to all devices. Two types of devices are classified into class I. The first type of class I device is comprised of those devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices (section 513(a)(1)(A)(i) of the act). The second type of class I device consists of those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device * * * but are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health and do not present a potential unreasonable risk of illness or injury (section 513(a)(1)(A)(ii) of the act). A ''potential unreasonable risk of illness or injury'' includes actual risk, as well as potential risk. Thus, the risk may be one demonstrated by reported injuries; i.e., medical device reports (MDR's), or it may simply be foreseeable. See H. Rept. 853, 94th Cong., 2d. sess. 36 (1990).

The effect of classifying a device into class II is to require the device to meet general controls as well as special controls, which together provide reasonable assurance of the safety and effectiveness of the device. Class II devices include devices which cannot be classified in class I because general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards (see section 513(a)(1)(B) of the act).

The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application (PMA) that includes information concerning safety and effectiveness of the device.

II. Reclassification Criteria

Pursuant to section 513(e)(1) of the act, based on new information respecting a device, the agency may, upon its own initiative, by regulation change a device's classification and revoke, because of the change in classification, any regulation or requirement in effect with respect to such device under sections 514 or 515 of the act (21 U.S.C. 360d or 21 U.S.C. 360e). The new information respecting a device must demonstrate that either more regulatory control is needed to provide reasonable assurance of the device's safety and effectiveness or that less regulatory control is sufficient to provide such assurance. The following developments have produced new information relating to the devices which justifies reclassifying these devices.

A. The SMDA Provisions

In the **Federal Register** of September 14, 1984 (49 FR 36326 at 36348), FDA issued MDR regulations (21 CFR part 803). These regulations required manufacturers and importers of medical devices, including diagnostic devices, to report to FDA whenever the manufacturer or importer becomes aware of information that reasonably suggests that one of its marketed devices: (1) May have caused or contributed to a death or serious injury, or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Because these MDR regulations were not always adequate to protect the public health, the SMDA, which was signed into law on November 28, 1990, added the following MDR requirements and provisions, as well as other requirements and provisions:

(1) Section 518(e) of the act (21 U.S.C. 360h(e)) allows FDA to order a manufacturer or other appropriate firm to immediately cease distribution of a device and immediately notify health professionals and device user facilities to cease using the device after FDA has determined that there is a reasonable probability that the device would cause serious adverse health consequences or death.

(2) Section 519(a)(6) of the act (21 U.S.C. 360i(a)(6)) requires distributors of medical devices to report to FDA adverse experiences related to devices, and to submit copies of reports to device manufacturers.

(3) Section 519(b)(1) of the act (21 U.S.C. 360i(b)(1)) requires certain device user facilities (hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities which are not physician's offices) to report to FDA and the manufacturer, if known, deaths related to medical devices. Additionally, under this section, device user facilities are required to report to the manufacturer, or to FDA if the manufacturer is unknown, device-related serious illnesses or injuries. User facilities are also required to submit a semiannual report to FDA summarizing the reports they have submitted. Under this section, reporting is limited to events involving a facility's patients.

(4) Section 519(d) of the act (21 U.S.C. 360e(d)) requires manufacturers, importers, and distributors to certify to FDA the number of reports submitted in a year or the fact that no such reports have been submitted to the agency.

(5) Section 519(f) of the act (21 U.S.C. 360i(f)) requires manufacturers, importers, and distributors to report to FDA any removals or corrections of a device intended to reduce a risk to health posed by a device or to remedy a violation of the act which may present a risk to health.

These new authorities, which are applicable to all devices, including class I devices, will enable FDA to monitor the 112 devices proposed for reclassification more closely and to take appropriate remedial action, if necessary.

B. The Device Priority Model

Assuring the safety and effectiveness of all medical devices is an extremely complex and difficult task in light of the number and diversity of devices being marketed. Thus, in 1989, FDA's Office of Standards and Regulations established a Device Priority Model (DPM) to help set priorities for all medical device activities (Ref. 1).

The DPM uses six general parameters, referred to as evaluation factors, to describe and calculate a priority score for each device. The six evaluation factors used in the model are: Frequency of mortality, effectiveness, health benefit, frequency of use, frequency of serious injury, and frequency of less serious injury.

The values for these evaluation factors are combined linearly using weights which represent the relative societal importance of each evaluation factor. The evaluation factors and assigned model weights are as follows: Frequency of death .38, frequency of serious injury .30, frequency of less serious injury .12, frequency of use .08, health benefit .08, and effectiveness .04.

After assigning model weights to the evaluation factors, a three level scoring scheme is applied. Predetermined

ranges of the values of the evaluation factors were used to determine a high, medium, or low scoring level. For frequency of death, frequency of serious injury, and frequency of less serious injury, the correspondence between the estimates for evaluation factor values and evaluation factor scores are: High = 100, medium = 50, and low = 0. The corresponding evaluation factor values and evaluation factor scores for the remaining three evaluation factors (frequency of use, health benefit, and effectiveness) are reversed; low = 100, medium = 50, high = 0. The reason for this reversal is as follows: If one considers two devices that are associated with an equal annual incidence of deaths and injuries, the device that should have the highest priority for FDA action is the one with the highest intrinsic risk per use, the lowest health benefit, and the lowest effectiveness.

The resulting number is called the priority score and is calculated by multiplying the score by the weight. The priority score is used to flag devices that may require more extensive analysis.

C. The Three Tier System

In early 1994, FDA's Office of Device Evaluation undertook a risk assessment of all devices in order to ensure the proper allocation of resources for the review process. Under this risk assessment, all class I, class II, and class III devices were placed into one of three tiers based upon the inherent risk associated with each device. Tier 3 devices include many first and second of a kind devices utilizing new technology or having new intended uses(s), as well as other devices determined by their inherent risk to require an intensive review. These tier 3 devices require intensive scientific and labeling review by a review team as well as advisory panel input. Most tier 3 devices require the submission of a premarket approval application. Tier 2 devices include devices which require routine scientific and labeling review. This tier encompasses the majority of 510(k)'s and select PMA's. Tier 1 devices include devices which require only a focused labeling review for intended use/indications for use and devices which have: (1) A score in the DPM less than 30 and/or; (2) no MDR death reports in any of the previous 3 years; and (3) 10 or fewer total injury reports in the previous 3 years.

III. Class II Devices To Be Reclassified Into Class I

The agency has carefully reviewed all available information concerning all class II, tier 1 devices. Based on this review, FDA is now proposing to reclassify 112 class II, tier 1 devices into class I. All of these devices were originally classified into class II under the original definition of class II devices which was defined as ''a device which cannot be classified as a class I because general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, for which there is sufficient information to establish a performance standard to provide such assurance, * * *.'' See H. Rept. 94–853, 94th Cong., 2d sess. 107 (1976). To date, no performance standards have been promulgated. Thus, any risks presented by these 112 devices have been addressed solely by general controls. The lack of adverse events or threats to the public health reported in the new information described above, supports agency's conclusion that general controls are adequate to provide reasonable assurance of safety and effectiveness for the 112 devices. In light of the new SMDA requirements, the new information gathered in response to the development of the DPM, and the three tier risk assessment system, FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of these devices.

IV. Proposed Exemptions

Section 513(d)(2)(A) of the act authorizes FDA to exempt, by regulation, a generic type of class I device from, among other things, the requirement of premarket notification in section 510(k) of the act (21 U.S.C. 360(k)). Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA. When FDA issued proposed regulations classifying preamendments devices, the agency focused on granting exemptions from the requirement of premarket notification principally when the advisory panels included them in their recommendations to the agency. Subsequently, FDA decided to exempt certain additional class I devices from the requirement of premarket notification in order to reduce the number of unnecessary premarket notifications. Moreover, in accordance with the agency's policy of reducing the number of unnecessary premarket notifications, in the **Federal Register** of December 7, 1994 (59 FR 63005), FDA exempted 148 generic types of class I devices from the requirement of premarket notification, with limitations. These actions help to free agency resources for the review of more complex notifications to FDA.

A. Description of Proposed Exemptions

In considering whether to exempt additional class I devices from premarket notification, FDA focused on whether notification for the type of device is unnecessary for the protection of the public health. For the devices in this document, FDA has concluded that premarket notification is unnecessary primarily for the following reasons:

(1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials. When making these determinations, FDA generally has considered the frequency, persistence, cause, or seriousness of such claims or risks, as well as other factors deemed relevant.

(2) In general, the following factors apply: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that could affect safety and effectiveness will either: (i) Be readily detectable by users by visual examination or other means, such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) any changes in the device would not be likely to result in a change in the device's classification.

For the 124 devices, FDA has made the determinations described above based on its knowledge of the devices, including past experience and relevant reports or studies on device performance. Where FDA has concerns only about certain types of changes to a particular class I device, the agency is proposing a limited exemption from premarket notification for that generic type of device. A limited exemption will specify the types of changes to the device for which manufacturers are required to submit a premarket notification. For example, for some devices FDA is proposing to exempt the device from the requirement of premarket notification except when a manufacturer intends to use a different material.

FDA advises manufacturers that an exemption from the requirement of premarket notification is not an exemption from any of the other general controls under the act, including current good manufacturing practices (CGMP's), unless explicitly stated. Indeed, FDA's decision to propose 510(k) exemptions for these devices is based, in part, on the fact that compliance with CGMP's will help ensure product quality.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device will be based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change or modification to a device, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification are still required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device or a legally marketed device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or

(2) The modified device operates using a different fundamental scientific technology than used by the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Such changes or modifications to class I devices that are exempt from premarket notification would mean the exemption would no longer apply. Changes or modifications to devices that are not exempt from premarket notification requirements under any regulation must undergo a more comprehensive assessment to determine the impact of the change or modification on the device's safety and effectiveness. FDA intends to develop guidance clarifying when a change or modification to a device requires submission of a premarket notification as defined in 21 CFR 807.81(a)(3).

On the dates listed in Table I, FDA published final regulations classifying, among others, the devices listed below. When FDA classified these devices, the agency did not exempt them from the requirement of premarket notification. Based on the analysis described above, FDA has now determined that premarket notification with respect to the devices listed below is unnecessary for the protection of the public health and will not advance FDA's public health mission. This approach is consistent with the recommendation in the May 1993 report of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, entitled ''Less Than the Sum of its Parts Reforms Needed in the Organization, Management, and Resources of The Food and Drug Administration's Center for Devices and Radiological Health.''

As stated above, earlier this year, the Office of Device Evaluation undertook a risk assessment of all devices in order to ensure the proper allocation of resources in the review process. All of the class II devices listed below were placed in tier 1, the category of devices which have a minimal inherent risk and whose review focuses upon intended use. As stated in the **Federal Register** of July 21, 1994 (59 FR 37378), FDA is now proposing to reclassify 112 class II, tier 1 devices into class I and exempt these devices, along with 12 class I, tier 1 devices, from the requirement of premarket notification, with limitations.

FDA is proposing to exempt from the requirement of premarket notification, with limitations, the 124 generic type of devices (including 12 already classified generic types of class I devices; chromatographic separation material for clinical use (§ 862.2230 (21 CFR 862.2230)); dental floss (§ 872.6390 (21 CFR 872.6390)); acoustic chamber for audiometric testing (§ 874.1060 (21 CFR 874.1060)); ear, nose, and throat bur (§ 874.4140 (21 CFR 874.4140)); nasopharyngeal catheter (§ 874.4175 (21 CFR 874.4175)); otoscope (§ 874.4770 (21 CFR 874.4770)); nonpowered breast pump (§ 884.5150 (21 CFR 884.5150)); unscented menstrual pad (§ 884.5435 (21 CFR 884.5435)); cast removal instrument (§ 888.5960 (21 CFR 888.5960)); flotation cushion (§ 890.3175 (21 CFR 890.3175)); traction accessory (§ 890.5925 (21 CFR 890.5925)); and personnel protective shield (§ 892.6500 (21 CFR 892.6500)) listed below:

TABLE 1

CFR part	Title	Number of devices proposed to be exempt
862	Clinical Chemistry and Clinical Toxicology Devices; May 1, 1987 (52 FR 16102)	1
866	Immunology and Microbiology Devices; November 8, 1982 (47 FR 50814)	5
868	Anesthesiology Devices; July 16, 1982 (47 FR 31130)	40
870	Cardiovascular Devices; February 5, 1980 (45 FR 7904)	10
872	Dental Devices; August 12, 1987 (52 FR 300820); November 20, 1990 (55 FR 484360)	4
874	Ear, Nose, and Throat Devices; November 6, 1986 (51 FR 40378)	6
876	Gastroenterology-Urology Devices; November 23, 1983 (48 FR 53012); June 12, 1989 (54 FR 25042)	11
878	General and Plastic Surgery Devices; June 24, 1988 (53 FR 23856)	4
880	General Hospital and Personal Use Devices; October 21, 1980 (45 FR 69678)	4
882	Neurological Devices; September 4, 1979 (44 FR 51726)	2
884	Obstetrical and Gynecological Devices; February 26, 1980 (45 FR 12682)	11
886	Ophthalmic Devices; September 2, 1987 (52 FR 33346); November 20, 1990 (55 FR 48436)	4
888	Orthopedic Devices; September 4, 1987 (52 FR 33686); November 20, 1990 (55 FR 48436)	3
890	Physical Medicine Devices; November 23, 1983 (48 FR 53032)	12
892	Radiology Devices; January 20, 1988 (53 FR 1554)	7
Total		124

TABLE 2.—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

CFR section	Device
862.2230	Chromatographic separation material for clinical use.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of device listed in Table 2 above.

TABLE 3.—IMMUNOLOGY AND MICROBIOLOGY DEVICES

CFR section	Device
866.2160	Coagulase plasma.
866.3720	Streptococcus spp. exoenzyme reagents.
866.5520	Immunoglobulin G (Fab fragment specific) immunological test system.
886.5530	Immunoglobulin G (Fc fragment specific) immunological test system.
866.5860	Total spinal fluid immunological test system.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 3 above.

TABLE 4.—ANESTHESIOLOGY DEVICES

CFR section	Device
868.1100	Arterial blood sampling kit.
868.1575	Gas collection vessel.
868.1870	Gas volume calibrator.
868.2300	Bourdon gauge flowmeter.
868.2320	Uncompensated thorpe tube flowmeter.
868.2340	Compensated thorpe tube flowmeter.
868.2350	Gas calibration flowmeter.
868.2610	Gas pressure gauge.
868.2620	Gas pressure calibrator.
868.2700	Pressure regulator.
868.2875	Differential pressure transducer.
868.2885	Gas flow transducer.
868.2900	Gas pressure transducer.
868.5100	Nasopharyngeal airway.
868.5110	Oropharyngeal airway.
868.5240	Anesthesia breathing circuit.
868.5300	Carbon dioxide absorbent.
868.5310	Carbon dioxide absorber.
868.5320	Reservoir bag.
868.5375	Heat and moisture condenser (artificial nose).
868.5460	Therapeutic humidifier for home use.
868.5530	Flexible laryngoscope.
868.5540	Rigid laryngoscope.
868.5550	Anesthetic gas mask.

TABLE 4.—ANESTHESIOLOGY DEVICES—Continued

CFR section	Device
868.5570	Nonrebreathing mask.
868.5580	Oxygen mask.
868.5590	Scavenging mask.
868.5600	Venturi mask.
868.5770	Tracheal tube fixation device.
868.5780	Tube introduction forceps.
868.5790	Tracheal tube stylet.
868.5810	Airway connector.
868.5820	Dental protector.
868.5860	Pressure tubing and accessories.
868.5975	Ventilator tubing.
868.5995	Tee drain (water trap).
868.6400	Calibration gas.
868.6820	Patient position support.
868.6885	Medical gas yoke assembly.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 4 above.

TABLE 5.—CARDIOVASCULAR DEVICES

CFR section	Device
870.2390	Phonocardiograph.
870.2600	Signal isolation system.
870.2620	Line isolation monitor.
870.2640	Portable leakage current alarm.
870.2810	Paper chart recorder.
870.3650	Pacemaker polymeric mesh bag.
870.3670	Pacemaker charger.
870.3690	Pacemaker test magnet.
870.3935	Prosthetic heart valve holder.
870.3945	Prosthetic heart valve sizer.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 5 above.

TABLE 6.—DENTAL DEVICES

CFR section	Device
872.1840	Dental x-ray position indicating device.
872.1850	Lead-lined position indicator.
872.4630	Dental operating light.
872.6390	Dental floss.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices in Table 6 listed above. The proposed exemption for dental floss (§ 872.6390 (21 CFR 872.6390)) is limited and would apply only when the device is composed of inert material and is not coated or impregnated with chemicals intended to provide a therapeutic benefit or interact with tissues of the oral cavity.

TABLE 7.—EAR, NOSE, AND THROAT DEVICES

CFR section	Device
874.1060	Acoustic chamber for audiometric testing.
874.1080	Audiometer calibration set.
874.4140	Ear, nose, and throat bur.
874.4175	Nasopharyngeal catheter.
874.4350	Ear, nose, and throat fiberoptic light source and carrier.
874.4770	Otoscope.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 7 above. The proposed exemption for the otoscope (§ 874.4770 (21 CFR 874.4770)) is limited and would apply only when used in the external ear canal.

TABLE 8.—GASTROENTEROLOGY-UROLOGY DEVICES

CFR section	Device
876.1075	Gastroenterology-urology biopsy instrument.
876.1400	Stomach pH electrode.
876.1500	Endoscope and accessories.
876.1800	Urine flow or volume measuring system.
876.4590	Interlocking urethral sound.
876.4890	Urological catheter and accessories.
876.5090	Suprapublic urological catheter and accessories.
876.5130	Urological catheter and accessories.
876.5450	Rectal dilator.
876.5520	Urethral dilator.
876.5540	Blood access device and accessories.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 8 above. The proposed exemption for the gastroenterology- urology biopsy instrument (§ 876.1075 (21 CFR 876.1075)) is limited and would apply only to the biopsy forceps cover and the nonelectric biopsy forceps. The proposed exemption for the endoscope and accessories (§ 876.1500 (21 CFR 876.1500)) is limited and would apply only to the following specified devices: Photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for

prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The proposed exemption for the urine flow or volume measuring system (§ 876.1800 (21 CFR 876.1800)) is limited and would apply only to the disposable, nonelectrical urine flow rate measuring device and the nonelectrical urinometer. The proposed exemption for the electrically powered urological table and accessories (§ 876.4890 (21 CFR 876.4890)) is limited and would apply only to stirrups. The proposed exemption for the suprapubic urological catheter and accessories (§ 876.5090 (21 CFR 876.5090)) is limited and would apply only to the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. The proposed exemption for the urological catheters and accessories (§ 876.5130 (21 CFR 876.5130)) is limited and would apply only to the ureteral stylet (guidewire), stylet for gastro-urological catheter, ureteral catheter holder, ureteral catheter adapter, and ureteral catheter connector. The proposed exemption for the urethral dilator (§ 876.5520 (21 CFR 876.5520)) is limited and would apply only to the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. Finally, the proposed exemption for the blood access device and accessories (§ 876.5540 (21 CFR 876.5540)) is limited and would apply only to the following accessories for both the implanted and the nonimplanted blood access device: Cannula clamp, disconnect forceps, crimp plier, tub plier, crimp ring, and joint ring.

TABLE 9.—GENERAL AND PLASTIC SURGERY DEVICES

CFR section	Device
878.4450	Nonabsorbable gauze for internal use.
878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology.
878.5350	Needle-type epilator.
878.5910	Pneumatic tourniquet.

FDA is proposing to grant an exemption from the requirement of premarket notification for the devices listed in Table 9 above. The proposed exemption for the laser surgical instrument for use in general and plastic surgery and in dermatology (§ 878.4810 (21 CFR 878.4810) is limited and would apply only to gas mixtures used as the lasing medium for this class of lasers.

TABLE 10.—GENERAL HOSPITAL AND PERSONAL USE DEVICES

CFR section	Device
880.2720	Patient scale.
880.2900	Clinical color change thermometer.
880.6320	AC-powered medical examination light.
880.5560	Temperature regulated water mattress.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 10 above.

TABLE 11.—NEUROLOGICAL DEVICES

CFR section	Device
882.1410	Electroencephalograph electrode/lead tester.
882.4325	Cranial drill handpiece (brace).

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 11 above.

TABLE 12.—OBSTETRICAL AND GYNECOLOGICAL DEVICES

CFR section	Device
884.1550	Amniotic fluid sampler (amniocentesis tray).
884.1640	Culdoscope and accessories.
884.1690	Hysteroscope and accessories.
884.1700	Hysteroscopic insufflator.
884.1720	Gynecologic laparoscope and accessories.
884.1730	Laparoscopic insufflator.
884.4530	Obstetric-gynecological specialized manual instrument.
884.5150	Nonpowered breast pump.
884.5425	Scented or scented deodorized menstrual pad.
884.5435	Unscented menstrual pad.
884.5900	Therapeutic vaginal douche apparatus.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 12 above. The proposed exemption for the culdoscope and accessories (§ 884.1640 (21 CFR 884.1640)) and the laparoscope and accessories (§ 884.1720 (21 CFR 884.1720)) are limited and would apply only to culdoscope and laparoscope accessories, respectively, that are not part of a specialized instrument or device delivery system and which do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope and laparoscope accessory instruments are limited to: Lens cleaning brush; biopsy brush; clip applier (without clips); applicator; cannula (without trocar or valves); ligature carrier/needle holder; clamp/hemostat/grasper; curette; instrument guide; ligature passing and knotting instrument; suture needle (without suture); retractor, mechanical (noninflatable); snare; stylet; forceps; dissector, mechanical (noninflatable); scissors; and suction/irrigation probe. The proposed exemption for the gynecological hysteroscope and accessories (§ 884.1690 (21 CFR 884.1690)) is limited and would apply only to the following manual accessories: Lens cleaning brush; cannula (without trocar or valves); clamp/hemostat/grasper; curette; instrument guide; forceps; dissector; mechanical (noninflatable); and scissors. The proposed exemption for the hysteroscopic or laparoscopic insufflator accessories (§§ 884.1700 and 884.1730 (21 CFR 884.1700 and 884.1730), respectively) is limited and would apply only to tubing and tubing/filter kits used for hysteroscopic or laparoscopic insufflation as single use tubing kits used for only one clinical purpose, i.e., pneumoperitoneum or intrauterine insufflation, but not both. The proposed exemption does not apply to accessories such as hysteroscopic introducer sheaths or Verres needles. The proposed exemption for the obstetric-gynecological specialized manual instruments (§ 884.4530 (21 CFR 884.4530)) is limited and would apply only to the following devices: Amniotome; uterine curette; cervical dilator (fixed-size bougies); cerclage needle; intrauterine device remover; uterine sound; and gynecological biopsy forceps. The proposed exemption for the nonpowered breast pump (§ 884.5150) is limited and would apply only if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects. The proposed exemption for the scented or scented deodorized menstrual pad (§ 884.5425 (21 CFR 884.5425)) and the unscented menstrual pad (§ 884.5435) is limited and would

apply only if the menstrual pad is made from cotton or rayon and the body contact material(s) are safety tested for dermal irritation, dermal sensitivity, acute toxicity, and mucosal irritation. Finally, the proposed exemption for the therapeutic vaginal douche apparatus (§ 884.5900 (21 CFR 884.5900)) is limited and would apply only to devices which operate by gravity feed.

TABLE 13.—OPHTHALMIC DEVICES

CFR section	Device
886.1405	Ophthalmic trial lens set.
886.1750	Skiascopic rack.
886.1760	Ophthalmic refractometer.
886.3200	Artificial eye.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 13 above. The proposed exemption for the artificial eye (§ 886.3200 (21 CFR 886.3200)) is limited and would apply only to devices made of the same materials, have the same chemical composition, and use the same manufacturing and disinfection processes as currently legally marketed devices.

TABLE 14.—ORTHOPEDIC DEVICES

CFR section	Device
888.1100	Arthroscope.
888.3000	Bone cap.
888.5960	Cast removal instrument.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 14 above. The proposed exemption for the arthroscope (§ 888.1100 (21 CFR 888.1100)) is limited and would apply only to the following manual arthroscope instruments: Cannulas, curettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knot pushers, suture punches, switching rods, and trocars.

TABLE 15.—PHYSICAL MEDICINE DEVICES

CFR section	Device
890.1575	Force-measuring platform.
890.1600	Intermittent pressure measurement system.
890.1615	Miniature pressure transducer.
890.3175	Flotation cushion.

TABLE 15.—PHYSICAL MEDICINE DEVICES—Continued

CFR section	Device
890.3760	Powered table.
890.5380	Powered exercise equipment.
890.5410	Powered finger exerciser.
890.5660	Therapeutic massager.
890.5925	Traction accessory.
890.5940	Chilling unit.
890.5950	Powered heating unit.
890.5975	Therapeutic vibrator.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 15 above.

TABLE 16.—RADIOLOGY DEVICES

CFR section	Device
892.1700	Diagnostic x-ray high voltage generator.
892.1760	Diagnostic x-ray housing assembly.
892.1770	Diagnostic x-ray tube mount.
892.1830	Radiologic patient cradle.
892.1880	Wall-mounted radiographic cassette holder.
892.5780	Light beam patient position indicator.
892.6500	Personnel protective shield.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 16 above. The proposed exemption for the personnel protective shield (§ 892.6500 (21 CFR 892.6500)) is limited and would only apply to devices whose labeling specifies the lead equivalence.

V. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. The Device Priority Model: Development and Applications, Office of Standards and Regulations, FDA, Rockville, MD, October 1989.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment or an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a proposal on small entities. Because this proposal would reduce a regulatory burden by exempting manufacturers of devices subject to the rule from the requirements or premarket notification, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VIII. Request for Comments

Interested persons may, on or before October 11, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Parts 862, 868, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 862.2230 is amended by revising paragraph (b) to read as follows:

§ 862.2230 Chromatographic separation material for clinical use.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

3. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 866.2160 is amended by revising paragraph (b) to read as follows:

§ 866.2160 Coagulase plasma.

* * * * *

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

5. Section 866.3720 is amended by revising paragraph (b) to read as follows:

§ 866.3720 Streptococcus spp. exoenzyme reagents.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

6. Section 866.5520 is amended by revising paragraph (b) to read as follows:

§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

7. Section 866.5530 is amended by revising paragraph (b) to read as follows:

§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

8. Section 866.5860 is amended by revising paragraph (b) to read as follows:

§ 866.5860 Total spinal fluid immunological test system.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 868—ANESTHESIOLOGY DEVICES

9. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

10. Section 868.1100 is amended by revising paragraph (b) to read as follows:

§ 868.1100 Arterial blood sampling kit.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

11. Section 868.1575 is amended by revising paragraph (b) to read as follows:

§ 868.1575 Gas collection vessel.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

12. Section 868.1870 is amended by revising paragraph (b) to read as follows:

§ 868.1870 Gas volume calibrator.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

13. Section 868.1975 is amended by revising paragraph (b) to read as follows:

§ 868.1975 Water vapor analyzer.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

14. Section 868.2300 is amended by revising paragraph (b) to read as follows:

§ 868.2300 Bourdon gauge flowmeter.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

15. Section 868.2320 is amended by revising paragraph (b) to read as follows:

§ 868.2320 Uncompensated thorpe tube flowmeter.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

16. Section 868.2340 is amended by revising paragraph (b) to read as follows:

§ 868.2340 Compensated thorpe tube flowmeter.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

17. Section 868.2350 is amended by revising paragraph (b) to read as follows:

§ 868.2350 Gas calibration flowmeter.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

18. Section 868.2610 is amended by revising paragraph (b) to read as follows:

§ 868.2610 Gas pressure gauge.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

19. Section 868.2620 is amended by revising paragraph (b) to read as follows:

§ 868.2620 Gas pressure calibrator.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

20. Section 868.2700 is amended by revising paragraph (b) to read as follows:

§ 868.2700 Pressure regulator.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

21. Section 868.2875 is amended by revising paragraph (b) to read as follows:

§ 868.2875 Differential pressure transducer.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

22. Section 868.2885 is amended by revising paragraph (b) to read as follows:

§ 868.2885 Gas flow transducer.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

23. Section 868.2900 is amended by revising paragraph (b) to read as follows:

§ 868.2900 Gas pressure transducer.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

24. Section 868.5100 is amended by revising paragraph (b) to read as follows:

§ 868.5100 Nasopharyngeal airway.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

25. Section 868.5110 is amended by revising paragraph (b) to read as follows:

§ 868.5110 Oropharyngeal airway.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

26. Section 868.5240 is amended by revising paragraph (b) to read as follows:

§ 868.5240 Anesthesia breathing circuit.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

27. Section 868.5300 is amended by revising paragraph (b) to read as follows:

§ 868.5300 Carbon dioxide absorbent.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

28. Section 868.5310 is amended by revising paragraph (b) to read as follows:

§ 868.5310 Carbon dioxide absorber.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

29. Section 868.5320 is amended by revising paragraph (b) to read as follows:

§ 868.5320 Reservoir bag.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

30. Section 868.5375 is amended by revising paragraph (b) to read as follows:

§ 868.5375 Heat and moisture condenser (artificial nose).

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

31. Section 868.5460 is amended by revising paragraph (b) to read as follows:

§ 868.5460 Therapeutic humidifier for home use.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

32. Section 868.5530 is amended by revising paragraph (b) to read as follows:

§ 868.5530 Flexible laryngoscope.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

33. Section 868.5540 is amended by revising paragraph (b) to read as follows:

§ 868.5540 Rigid laryngoscope.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

34. Section 868.5550 is amended by revising paragraph (b) to read as follows:

§ 868.5550 Anesthetic gas mask.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

35. Section 868.5570 is amended by revising paragraph (b) to read as follows:

§ 868.5570 Nonrebreathing mask.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

36. Section 868.5580 is amended by revising paragraph (b) to read as follows:

§ 868.5580 Oxygen mask.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

37. Section 868.5590 is amended by revising paragraph (b) to read as follows:

§ 868.5590 Scavenging mask.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

38. Section 868.5600 is amended by revising paragraph (b) to read as follows:

§ 868.5600 Venturi mask.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

39. Section 868.5770 is amended by revising paragraph (b) to read as follows:

§ 868.5770 Tracheal tube fixation device.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

40. Section 868.5780 is amended by revising paragraph (b) to read as follows:

§ 868.5780 Tube introduction forceps.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

41. Section 868.5790 is amended by revising paragraph (b) to read as follows:

§ 868.5790 Tracheal tube stylet.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

42. Section 868.5810 is amended by revising paragraph (b) to read as follows:

§ 868.5810 Airway connector.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

43. Section 868.5820 is amended by revising paragraph (b) to read as follows:

§ 868.5820 Dental protector.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

44. Section 868.5860 is amended by revising paragraph (b) to read as follows:

§ 868.5860 Pressure tubing and accessories.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

45. Section 868.5975 is amended by revising paragraph (b) to read as follows:

§ 868.5975 Ventilator tubing.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

46. Section 868.5995 is amended by revising paragraph (b) to read as follows:

§ 868.5995 Tee drain (water trap).

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

47. Section 868.6400 is amended by revising paragraph (b) to read as follows:

§ 868.6400 Calibration gas.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

48. Section 868.6820 is amended by revising paragraph (b) to read as follows:

§ 868.6820 Patient position support.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

49. Section 868.6885 is amended by revising paragraph (b) to read as follows:

§ 868.6885 Medical gas yoke assembly.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 870—CARDIOVASCULAR DEVICES

50. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

51. Section 870.2390 is amended by revising paragraph (b) to read as follows:

§ 870.2390 Phonocardiograph.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

52. Section 870.2600 is amended by revising paragraph (b) to read as follows:

§ 870.2600 Signal isolation system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

53. Section 870.2620 is amended by revising paragraph (b) to read as follows:

§ 870.2620 Line isolation monitor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

54. Section 870.2640 is amended by revising paragraph (b) to read as follows:

§ 870.2640 Portable leakage current alarm.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

55. Section 870.2810 is amended by revising paragraph (b) to read as follows:

§ 870.2810 Paper chart recorder.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

56. Section 870.3650 is amended by revising paragraph (b) to read as follows:

§ 870.3650 Pacemaker polymeric mesh bag.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

57. Section 870.3670 is amended by revising paragraph (b) to read as follows:

§ 870.3670 Pacemaker charger.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

58. Section 870.3690 is amended by revising paragraph (b) to read as follows:

§ 870.3690 Pacemaker test magnet.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

59. Section 870.3935 is amended by revising paragraph (b) to read as follows:

§ 870.3935 Prosthetic heart valve holder.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

60. Section 870.3945 is amended by revising paragraph (b) to read as follows:

§ 870.3945 Prosthetic heart valve sizer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 872—DENTAL DEVICES

61. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

62. Section 872.1840 is amended by revising paragraph (b) to read as follows:

§ 872.1840 Dental x-ray position indicating device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

63. Section 872.1850 is amended by revising paragraph (b) to read as follows:

§ 872.1850 Lead-lined position indicator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

64. Section 872.4630 is amended by revising paragraph (b) to read as follows:

§ 872.4630 Dental operating light.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

65. Section 872.6390 is amended by revising paragraph (b) to read as follows:

§ 872.6390 Dental floss.

* * * * *

(b) *Classification. Class I.* If the device is made of inert materials and is not coated or impregnated with chemicals intended to provide a therapeutic benefit or interact with tissues of the oral cavity, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 874—EAR, NOSE, AND THROAT DEVICES

66. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

67. Section 874.1060 is amended by revising paragraph (b) to read as follows:

§ 874.1060 Acoustic chamber for audiometric testing.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

68. Section 874.1080 is amended by revising paragraph (b) to read as follows:

§ 874.1080 Audiometer calibration test.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

69. Section 874.4140 is amended by revising paragraph (b) to read as follows:

§ 874.4140 Ear, nose, and throat bur.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

70. Section 874.4175 is amended by revising paragraph (b) to read as follows:

§ 874.4175 Nasopharyngeal catheter.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

71. Section 874.4350 is amended by revising paragraph (b) to read as follows:

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

72. Section 874.4770 is amended by revising paragraph (b) to read as follows:

§ 874.4770 Otoscope.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when used in the external ear canal.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

73. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

74. Section 876.1075 is amended by revising paragraph (b) to read as follows:

§ 876.1075 Gastroenterology-urology biopsy instrument.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the biopsy forceps cover and the nonelectric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

75. Section 876.1400 is amended by revising paragraph (b) to read as follows:

§ 876.1400 Stomach pH electrode.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

76. Section 876.1500 is amended by revising paragraph (b) to read as follows:

§ 876.1500 Endoscope and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

77. Section 876.1800 is amended by revising paragraph (b) to read as follows:

§ 876.1800 Urine flow or volume measuring system.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the disposable, nonelectrical urine flow rate measuring device, and nonelectrical urinometer. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

78. Section 876.4590 is amended by revising paragraph (b) to read as follows:

§ 876.4590 Interlocking urethral sound.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

79. Section 876.4890 is amended by revising paragraph (b) to read as follows:

§ 876.4890 Urological table and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards) for the electrically powered urological table and accessories.

(2) Class I for the manually powered table and accessories, and for stirrups for electrically powered table. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

80. Section 876.5090 is amended by revising paragraph (b) to read as follows:

§ 876.5090 Suprapubic urological catheter and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

81. Section 876.5130 is amended by revising paragraph (b) to read as follows:

§ 876.5130 Urological catheter and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the ureteral stylet (guidewire), stylet for gastro-urological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

82. Section 876.5450 is amended by revising paragraph (b) to read as follows:

§ 876.5450 Rectal dilator.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

83. Section 876.5520 is amended by revising paragraph (b) to read as follows:

§ 876.5520 Urethral dilator.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

84. Section 876.5540 is amended by revising paragraph (b)(3) and by adding new paragraph (b)(4) to read as follows:

§ 876.5540 Blood access device and accessories.

* * * * *

(b) * * *

(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section.

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring,

accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

* * * * *

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

85. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

86. Section 878.4450 is amended by revising paragraph (b) to read as follows:

§ 878.4450 Nonabsorbable gauze for internal use.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

87. Section 878.4810 is amended by revising paragraph (b) to read as follows:

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

* * * * *

(b) *Classification*. (1) Class II.

(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

88. Section 878.5350 is amended by revising paragraph (b) to read as follows:

§ 878.5350 Needle-type epilator.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

89. Section 878.5910 is amended by revising paragraph (b) to read as follows:

§ 878.5910 Pneumatic tourniquet.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

90. The authority citation for 21 CFR 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

91. Section 880.2720 is amended by revising paragraph (b) to read as follows:

§ 880.2720 Patient scale.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

92. Section 880.2900 is amended by revising paragraph (b) to read as follows:

§ 880.2900 Clinical color change thermometer.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

93. Section 880.5560 is amended by revising paragraph (b) to read as follows:

§ 880.5560 Temperature regulated water mattress.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

94. Section 880.6320 is amended by revising paragraph (b) to read as follows:

§ 880.6320 AC-powered medical examination light.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 882—NEUROLOGICAL DEVICES

95. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

96. Section 882.1410 is amended by revising paragraph (b) to read as follows:

§ 882.1410 Electroencephalograph electrode/lead tester.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

97. Section 882.4325 is amended by revising paragraph (b) to read as follows:

§ 882.4325 Cranial drill handpiece (brace).

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

98. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

99. Section 884.1550 is revised to read as follows:

§ 884.1550 Amniotic fluid sampler (amniocentesis tray.

(a) *Identification*. The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocenteses tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

100. Section 884.1640 is amended by revising paragraph (b) to read as follows:

§ 884.1640 Culdoscope and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: Lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

101. Section 884.1690 is amended by revising paragraph (b) to read as follows:

§ 884.1690 Hysteroscope and accessories.

* * * * *

(b) Classification. (1) Class II (performance standards).

(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device

delivery system, do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: Lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper, curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

102. Section 884.1700 is amended by revising paragraph (b) to read as follows:

§ 884.1700 Hysteroscopic insufflator.

* * * * *

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter fits which only include accessory instruments which are not used to effect intrauterine access, e.g., hysteroscopic introducer sheaths, etc., and single-use tubing kits used for only intrauterine insufflation. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

103. Section 884.1720 is amended by revising paragraph (b) to read as follows:

§ 884.1720 Gynecologic laparoscope and accessories.

* * * * *

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: The lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

104. Section 884.1730 is amended by revising paragraph (b) to read as follows:

§ 884.1730 Laparoscopic insufflator.

* * * * *

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter kits which include accessory instruments which are not used to effect intra-abdominal access, Verres needles etc., and single-use tubing kits used for only intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

105. Section 884.4530 is amended by revising paragraph (b) to read as follows:

§ 884.4530 Obstetric-gynecological specialized manual instrument.

* * * * *

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

106. Section 884.5150 is amended by revising paragraph (b) to read as follows:

§ 884.5150 Nonpowered breast pump.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.

107. Section 884.5425 is amended by revising paragraph (b) to read as follows:

§ 884.5425 Scented or scented deodorized menstrual pad.

* * * * *

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for menstrual pads made from cotton or rayon and for which the body contact material(s) and extracts from the absorbent material(s) are safety tested for dermal irritation, dermal sensitivity, acute toxicity, and mucosal irritation. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

108. Section 884.5435 is amended by revising paragraph (b) to read as follows:

§ 884.5435 Unscented menstrual pad.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device is made from cotton or rayon and for which the body contact material(s) and extracts from the absorbent material(s) are safety tested for dermal irritation, dermal sensitivity, acute toxicity, and mucosal irritation.

109. Section 884.5900 is amended by revising paragraph (b) to read as follows:

§ 884.5900 Therapeutic vaginal douche apparatus.

* * * * *

(b) *Classification.* (1) Class II (performance standards).

(2) Class I if the device is operated by gravity feed. Devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 886—OPHTHALMIC DEVICES

110. The authority citation for 21 CFR 886 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

111. Section 886.1405 is amended by revising paragraph (b) to read as follows:

§ 886.1405 Ophthalmic trial lens set.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

112. Section 886.1750 is amended by revising paragraph (b) to read as follows:

§ 886.1750 Skiascopic rack.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

113. Section 886.1760 is amended by revising paragraph (b) to read as follows:

§ 886.1760 Ophthalmic refractometer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

114. Section 886.3200 is revised to read as follows:

§ 886.3200 Artificial eye.

(a) *Identification.* An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if the device is made from the same materials, has the same chemical composition, and uses

the same manufacturing processes as currently legally marketed devices.

PART 888—ORTHOPEDIC DEVICES

115. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

116. Section 888.1100 is amended by revising paragraph (b) to read as follows:

§ 888.1100 Arthroscope.

* * * * *

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the following manual arthroscopic instruments: Cannulas, currettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knotpushers, suture punches, switching rods, and trocars. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

117. Section 888.3000 is amended by revising paragraph (b) to read as follows:

§ 888.3000 Bone cap.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

118. Section 888.5960 is amended by revising paragraph (b) to read as follows:

§ 888.5960 Cast removal instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 890—PHYSICAL MEDICINE DEVICES

119. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

120. Section 890.1575 is amended by revising paragraph (b) to read as follows:

§ 890.1575 Force-measuring platform.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

121. Section 890.1600 is amended by revising paragraph (b) to read as follows:

§ 890.1600 Intermittent pressure measurement system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

122. Section 890.1615 is amended by revising paragraph (b) to read as follows:

§ 890.1615 Miniature pressure transducer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

123. Section 890.3175 is amended by revising paragraph (b) to read as follows:

§ 890.3175 Flotation cushion.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

124. Section 890.3760 is amended by revising paragraph (b) to read as follows:

§ 890.3760 Powered table.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

125. Section 890.5380 is amended by revising paragraph (b) to read as follows:

§ 890.5380 Powered exercise equipment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

126. Section 890.5410 is amended by revising paragraph (b) to read as follows:

§ 890.5410 Powered finger exerciser.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

127. Section 890.5660 is amended by revising paragraph (b) to read as follows:

§ 890.5660 Therapeutic massager.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

128. Section 890.5925 is amended by revising paragraph (b) to read as follows:

§ 890.5925 Traction accessory.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

129. Section 890.5940 is amended by revising paragraph (b) to read as follows:

§ 890.5940 Chilling unit.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

130. Section 890.5950 is amended by revising paragraph (b) to read as follows:

§ 890.5950 Powered heating unit.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

131. Section 890.5975 is amended by revising paragraph (b) to read as follows:

§ 890.5975 Therapeutic vibrator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 892—RADIOLOGY DEVICES

132. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

133. Section 892.1700 is amended by revising paragraph (b) to read as follows:

§ 892.1700 Diagnostic x-ray high voltage generator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

134. Section 892.1760 is amended by revising paragraph (b) to read as follows:

§ 892.1760 Diagnostic x-ray tube housing assembly.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

135. Section 892.1770 is amended by revising paragraph (b) to read as follows:

§ 892.1770 Diagnostic x-ray tube mount.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

136. Section 892.1830 is amended by revising paragraph (b) to read as follows:

§ 892.1830 Radiologic patient cradle.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

137. Section 892.1880 is amended by revising paragraph (b) to read as follows:

§ 892.1880 Wall mounted radiographic cassette holder.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

138. Section 892.5780 is amended by revising paragraph (b) to read as follows:

§ 892.5780 Light beam patient position indicator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

139. Section 892.6500 is amended by revising paragraph (b) to read as follows:

§ 892.6500 Personnel protective shield.

* * * * *

(b) *Classification.* Class I. If the device's labeling specifies the lead equivalence, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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